PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

ORILISSA
(elagolix)

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS
Orilissa is indicated for the management of moderate to severe pain associated with endometriosis.

Limitations of Use:
Limit the duration of use based on the dose and coexisting condition.

COVERAGE CRITERIA

Moderate to Severe Pain Associated with Endometriosis
Authorization may be granted when the requested drug is being prescribed for the management of moderate to severe pain associated with endometriosis when ALL of the following criteria are met:

- The patient has NOT received the maximum recommended treatment course of 12 months of Lupron Depot or Lupaneta Pack OR 6 months of Synarel or Zoladex
- The patient meets ONE of the following:
  - If the patient has not previously received treatment with an elagolix-containing product (e.g., Oriahnn, Orilissa) or a relugolix-containing product (e.g., Myfembree), the patient will receive 150 mg once daily of the requested drug OR 200 mg twice daily of the requested drug
  - If the patient has previously received treatment with an elagolix-containing product (e.g., Oriahnn, Orilissa) or a relugolix-containing product (e.g., Myfembree), the patient has not already received ANY of the following: greater than or equal to 24 cumulative months of treatment with elagolix-containing products (e.g., Oriahnn, Orilissa) and/or relugolix-containing products (e.g., Myfembree), greater than or equal to 6 months of treatment with Orilissa 200 mg twice daily

DURATION OF APPROVAL (DOA)
- 2634-A: Total additive duration: 24 months (see chart)

Cumulative months of prior treatment with an elagolix- and/or relugolix-containing product	Duration of Approval (in months)
No prior treatment	12
≤ 12	12
13	11
14	10
15	9
16	8
17	7
18	6
19	5
20	4
21	3

22	2
23	1

REFERENCES

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2. Lupron Depot [package insert]. North Chicago, IL: AbbVie Inc.; October 2023.
3. Myfembree [package insert]. Brisbane, CA: Myovant Sciences, Inc.; August 2023.
4. Oriahnn [package insert]. North Chicago, IL: AbbVie Inc.; June 2023.
5. Orilissa [package insert]. North Chicago, IL: AbbVie Inc.; June 2023.
6. Synarel [package insert]. New York, NY: Pfizer Inc.; January 2023.
7. Zoladex 3.6 mg [package insert]. Deerfield, IL: TerSera Therapeutics LLC; March 2023.
8. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed December 06, 2023.
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10. Schrager S, Falleroni J, Edgoose J. Evaluation and treatment of endometriosis. *Am Fam Physician*. 2013;87(2):107-13.
11. Management of endometriosis. Practice Bulletin No. 114. American College of Obstetricians and Gynecologists. *Obstet Gynecol.* 2010;116:223-236.
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